REMARKS

Claims 1-5 and 7-24 are pending in the present application with claims 1-5 and 7-18 withdrawn from consideration. Accordingly, claims 19-24 are currently before the Examiner. Claim 19 is amended herein. Support for the amendments can be found on pages 19-20 of the application, as filed. New claims 23 and 24 have been added. Favorable consideration of the pending claims is respectfully requested.

Claims 19-22 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,004,967 to McMahon et al. (hereinafter "McMahon") in view of U.S. Patent No. 6,416,786 to Mulye et al. (hereinafter "Mulye") and U.S. Publication No. US2003/0230488 A1 to Lee et al. (hereinafter "Lee") as evidenced by www.wikipedia.com.

The Examiner asserts that McMahon discloses a method for determining the solubility of the pharmaceutical compound A1 in various excipients. The Examiner cites Table 4, which lists several excipients used for solubility testing of A1. The Examiner acknowledges, however, that McMahon fails to disclose or suggest conducting the experiments in an array format, as well as the step of dispensing less than 250 microliters of the excipient using a positive displacement pump. The Examiner also acknowledges that McMahon fails to disclose mixing excipients to explore the synergistic effects.

The Examiner cites Lee and Mulye for such disclosure. In particular, the Examiner asserts that Lee discloses an apparatus for conducting solubility tests including a positive displacement pump. According to the Examiner, it would have been obvious for one of ordinary skill in the art to conduct the solubility test of McMahon using the apparatus of Lee.

The Examiner further asserts that Mulye discloses that it is well known to mix excipients because certain excipient mixtures exhibit unexpected synergistic effects. According to the Examiner, in view of Mulye, it would have been obvious to mix excipients in the solubility test of McMahon to explore the synergistic effects of certain excipient mixtures. The Examiner further asserts that it would have been obvious to one of ordinary skill in the art to rank the compounds based on solubility because organizing test data is within the skill of one of ordinary skill in the art.

Applicants have amended claim 19 herein to further define the invention. In particular, amended claim 19 requires the additional method steps of: "(d) further identifying samples wherein all of the compound-of-interest dissolved and thereby do not contain solid; (e) contacting each of the identified solid-free samples with a liquid that simulates gastric fluids and analyzing the samples for one or more physical changes selected from the group consisting of precipitation, phase separation, suspension, emulsion and degradants; and (f) ranking the samples based on the one or more physical changes."

More specifically, pages 19-20 of the application describe the additional method steps in which solid-free samples are contacted with simulated gastric fluids and then further analyzed for various physical changes. Such physical changes can include formation of separate phases, or the presence of a precipitate, suspension, emulsion or degradants. The samples then are ranked based on these physical changes. As explained on page 19 of the application, such analysis may be helpful in the development of an oral dosage form that provides an active pharmaceutical agent in a bioavailable form.

None of the cited references disclose or suggest Applicants' amended claim 19, which requires these additional method steps. McMahon is directed to methods and compositions for treating skin disorders with a quinazoline derivative. McMahon merely lists the solubility of one of its compounds individually in several excipients, and contains no disclosure of relevance to Applicants' amended method claims. Lee simply discloses the preparation of microfluidic devices for the application of rapid electrophoretic separation. Thus, Lee also contains no disclosure of relevance to the screening method recited in Applicants' amended claims. Mulye merely relates to sustained release tablet dosage forms and also contains no disclosure of relevance to the screening method recited in Applicants' amended claims. Therefore, the combination of McMahon, Lee and Mulye fails to render Applicants' amended claims *prima facie* obvious.

In view thereof, Applicants respectfully submit that amended claim 19, and thus claims 20-24 which depend therefrom, are patentable over McMahon, Lee and Mulye, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this Amendment to Deposit Account No. 10-0750/TPI5020USNP/JML.

Respectfully submitted,

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